

## WHAT IS CLAIMED IS:

1           1. In a blood dialysis system including a dialysis machine and an  
2 extracorporeal circuit, a diafiltration module adapted to be connected to at least one of the  
3 dialysis machine and the extracorporeal circuit, the diafiltration module comprising:

4               a first conduit having a first end and an opposing second end, the first end  
5 for receiving a first fluid from the dialysis machine and the second end for discharging a  
6 dialysate fluid to the dialysis machine;

7               a second conduit in selective communication with the first conduit such that  
8 the second conduit selectively receives a diverted amount of the first fluid from the first  
9 conduit, the second conduit communicating with at least one sterilizing filter for filtering  
10 the diverted amount of the first fluid to produce a substitution fluid, wherein one end of the  
11 second conduit is configured to deliver the substitution fluid to the extracorporeal circuit;  
12 and

13              a control unit responsive to at least one of (a) a first detected characteristic  
14 of one of the first fluid and the dialysate fluid and (b) a second detected characteristic of  
15 blood within the extracorporeal circuit, the control unit being configured to prevent flow of  
16 the substitution fluid to the extracorporeal circuit when at least one of the first and second  
17 characteristics meets a prescribed criteria.

1           2.     The diafiltration module according to claim 1, wherein the first  
2 detected characteristic comprises a flow rate of one of the first fluid and the dialysate fluid.

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1                   3.       The diafiltration module according to claim 1, wherein the second  
2 detected characteristic comprises a flow rate of the blood.

1                   4.       The diafiltration module according to claim 1, further including:  
2                   a first flow meter disposed within the first conduit for detecting a flow rate  
3 of one of the first fluid and the dialysate fluid, the first flow meter in communication with  
4 the control unit; and

5                   a second flow meter disposed within the extracorporeal circuit for detecting  
6 a flow rate of the blood, the second flow meter in communication with the control unit.

1                   5.       The diafiltration module according to claim 1, further including:  
2                   a substitution fluid pump disposed within the second conduit for diverting  
3 the amount of the first fluid from first conduit to the second conduit.

1                   6.       The diafiltration module according to claim 5, further including:  
2                   a pressure transducer disposed within the second conduit upstream of the  
3 substitution pump for detecting a pressure of the diverted fluid within the second conduit,  
4 wherein the pressure transducer communicates with the control unit which signals the  
5 substitution fluid pump to turn off when the detected pressure is a below a threshold  
6 pressure value.

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1                   7.       The diafiltration module according to claim 1, further including:

2                   a pinch valve disposed within the second conduit for controlling the flow of  
3 the substitution fluid through the second conduit, the pinch valve being in communication  
4 with the control unit; and

5                   a substitution fluid pump disposed within the second conduit upstream of  
6 the at least one sterilizing filter for diverting the amount of the first fluid from the first  
7 conduit to the second conduit, the substitution fluid pump being in communication with  
8 the control unit.

1                   8.       The diafiltration module according to claim 7, further including:

2                   a pressure transducer disposed within the second conduit downstream of the  
3 substitution fluid pump for detecting a pressure within the second conduit, the pressure  
4 transducer in communication with the control unit; wherein the control unit controls the  
5 position of the pinch valve based on input received from the substitution fluid pump and  
6 the pressure transducer.

7                   9.       The diafiltration module according to claim 8, further including:

8                   an optical sensor disposed within the second conduit downstream of the at  
9 least one sterilizing filter for detecting transmittance of fluid contained in the second  
10 conduit downstream of the at least one sterilizing filter, the optical sensor being in  
11 communication with the control unit, wherein the optical sensor includes a light source and  
12 a photo-detector to detect a loss of transmittance of light through the fluid contained with  
13 the second conduit downstream of the at least one sterilizing filter, wherein the control unit

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14 controls the position of the pinch valve also based on input received from optical sensor.

1 10. The diafiltration module according to claim 8, wherein the control  
2 unit signals the pinch valve to open when (a) the substitution fluid pump is operating and  
3 the diverted fluid is pumped within the second conduit towards the at least one sterilizing  
4 filter; and (b) the pressure transducer detects a minimum pressure that assures that the  
5 substitution fluid flow remains in a forward direction into the extracorporeal circuit when  
6 the pinch valve opens.

1 11. The diafiltration module according to claim 9, wherein the pinch  
2 valve is closed by the control unit when the optical sensor detects blood in the second  
3 conduit.

1 12. The diafiltration module according to claim 1, further including:  
2 a substitution fluid pump disposed within the second conduit for  
3 diverting the amount of the first fluid from the first conduit to the second conduit, the  
4 substitution fluid pump being in communication with the control unit; and  
5 a flow switch disposed within the first conduit for detecting a flow  
6 rate within the first conduit, the flow switch being positionable between an ON position  
7 and an OFF position with the position of the flow switch being inputted to the control unit  
8 for controlling the operation of the substitution fluid pump.

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13. The diafiltration module according to claim 12, wherein the flow switch comprises one of a thermal flow switch and a mechanical flow switch.

14. The diafiltration module according to claim 1, further including:  
a substitution fluid pump disposed within the second conduit for diverting the amount of the first fluid from the first conduit to the second conduit, the substitution fluid pump being in communication with the control unit;

a blood pump disposed within the extracorporeal circuit for transporting blood through the extracorporeal circuit; and

wherein the second detected characteristic of blood comprises pressure pulses in the extracorporeal circuit, the detection of pressure pulses being inputted to the control unit to signal whether the blood pump is operating below a predetermined threshold value, the pressure pulses being processed by the control unit as feedback control input for controlling operation of the substitution pump.

15. The diafiltration module according to claim 14, further including:  
a drip chamber disposed within the extracorporeal circuit, the drip chamber having one or more pressure monitoring ports; and  
a pressure transducer that is in fluid contact with one of the pressure monitoring ports of the drip chamber, the pressure transducer detecting the pressure pulses in the extracorporeal circuit.

1 16. The diafiltration module according to claim 14, further including:  
2 a surface mounted pressure transducer that is in contact with a portion of a  
3 conduit defining the extracorporeal circuit, the surface mounted pressure transducer  
4 detecting the pressure pulses in the extracorporeal circuit.

1 17. The diafiltration module according to claim 14, wherein the control  
2 unit monitors a time interval between successive pressure pulses detected in the  
3 extracorporeal circuit such that the substitution fluid pump is turned to the OFF position by  
4 the control unit if one of (a) no pressure pulses are detected and (b) if the timer interval  
5 exceeds a predetermined value.

1 18. The diafiltration module according to claim 1, wherein the first fluid  
2 and the dialysate fluid are the same fluid.

1 19. The diafiltration module according to claim 1, wherein the first  
2 detected characteristic comprises a temperature decay measurement of the dialysate fluid.

1 20. The diafiltration module according to claim 1, wherein the second  
2 detected characteristic comprises a temperature decay measurement of the blood.

1 21. The diafiltration module according to claim 1, wherein the first  
2 detected characteristic comprises a temperature decay measurement of the dialysate fluid

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1 and the second detected characteristic comprises a temperature decay measurement of the  
2 blood and the diafiltration module further includes:

3 a first temperature sensing device for detecting the temperature of one of  
4 the first fluid and the dialysate fluid in the first conduit, the first temperature sensing  
5 device in communication with the control unit and inputting the detected temperature to  
6 the control unit;

7 a second temperature sensing device for detecting the temperature of blood  
8 in the extracorporeal circuit, the second temperature sensing device in communication with  
9 the control unit and inputting the detected temperature to the control unit; and

10 wherein the control unit is configured to detect a decrease in flow rate of  
11 one of the first fluid and the dialysate fluid by monitoring the detected temperature  
12 inputted from the first temperature sensing device and a decrease in a blood flow rate  
13 within the extracorporeal circuit by monitoring the detected temperature inputted from the  
14 second temperature sensing device.

1 22. The diafiltration module according to claim 21, wherein the first  
2 temperature sensing device is disposed in one of (a) a location inside of the first conduit  
3 and (b) on an outer surface of the first conduit.

1 23. The diafiltration module according to claim 22, wherein the first  
2 temperature sensing device comprises one of a thermistor and thermocouple that is  
3 disposed inside of the first conduit.

1           24.    The diafiltration module according to claim 21, wherein the second  
2   temperature sensing device is disposed in one of (a) a location inside of a conduit defining  
3   the extracorporeal circuit and (b) on an outer surface of the conduit defining the  
4   extracorporeal circuit.

1           25.    The diafiltration module according to claim 20, wherein the  
2   temperature decay measurement is determined as one of (a) a change in temperature from a  
3   fixed set point and (b) a change in temperature per unit time.

1           26.    The diafiltration module according to claim 22, wherein the first  
2   temperature sensing device comprises one of a thermistor and thermocouple that is  
3   disposed inside of the first conduit.

1           27.    The diafiltration module according to claim 1, wherein the second  
2   detected characteristic comprises a rotational speed measurement of a blood pump  
3   disposed within the extracorporeal circuit and wherein the prescribed criteria comprises a  
4   minimum rotational speed such that once the detected rotational speed measurement falls  
5   below the minimum rotational speed, the control unit prevents flow of the substitution  
6   fluid.

1           28.    The diafiltration module according to claim 27, further including:  
2   a tachometer device that measures the rotational speed of the blood pump.

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1                   29.     The diafiltration module according to claim 1, wherein the second  
2 detected characteristic comprises a fluid level fluctuation of the blood within a drip  
3 chamber that is provided along the extracorporeal circuit and wherein the prescribed  
4 criteria is when the fluid level fluctuation is below an acceptable fluid level fluctuation  
5 value, thereby preventing the flow of substitution fluid to the extracorporeal circuit.

1                   30.     The diafiltration module according to claim 29, further including:  
2 a substitution fluid pump disposed within the second conduit for diverting  
3 the amount of the first fluid from the first conduit to the second conduit, the substitution  
4 fluid pump being in communication with the control unit; and

5                   wherein the control unit detects whether a blood pump disposed within the  
6 extracorporeal circuit is operating within prescribed acceptable operating conditions by  
7 detecting the fluid level fluctuations in the drip chamber such that if the detected fluid  
8 level fluctuation is below an acceptable fluid level fluctuation value, the substitution fluid  
9 pump is turned to the OFF position.

1                   31.     The diafiltration module according to claim 1, wherein the first  
2 detected characteristic comprises a flow rate detected by inductively monitoring a current  
3 applied to an inlet valve that is disposed within a conduit that carries the first fluid from  
4 the dialysis machine to the first conduit.

1                   32.     The diafiltration module according to claim 1, wherein the second  
2 detected characteristic comprises a flow rate detected by inductively monitoring a current

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3 applied to a motor that drives a blood pump disposed within the extracorporeal circuit.

1 33. The diafiltration module according to claim 31, further including:  
2 a first inductive current clamp disposed around wires leading to the inlet  
3 valve, the first inductive current clamp in communication with the control unit, the control  
4 unit preventing flow of substitution fluid when the first inductive current clamp detects an  
5 absence of current.

1 34. The diafiltration module according to claim 32, further including:  
2 a second inductive current clamp disposed around wires leading to the  
3 blood pump, the second inductive current clamp in communication with the control unit  
4 which prevents the flow of substitution fluid when the second inductive current clamp  
5 detects an absence of current.

1 35. The diafiltration module according to claim 1, wherein the second  
2 detected characteristic comprises a blood flow rate detected by sensing vibrations  
3 generated by a blood pump that is disposed in the extracorporeal circuit.

1 36. The diafiltration module according to claim 35, wherein the  
2 vibrations are sensed mechanically or acoustically.

1 37. In a blood dialysis system including a dialysis machine that includes  
2 a source of dialysate fluid and an extracorporeal circuit, a method of preventing flow of

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3 substitution fluid to the extracorporeal circuit comprising the steps of:

4 providing a diafiltration module including a first conduit having a first end  
5 and a second end for carrying dialysate fluid and a second conduit in selective  
6 communication with the first conduit such that the second conduit selectively receives a  
7 diverted amount of the dialysate fluid, the diafiltration module further including at least  
8 one sterilizing filter in fluid communication with the second conduit for filtering the  
9 diverted dialysate fluid to produce the substitution fluid;

10 fluidly connecting the first end of the first conduit to the dialysis machine  
11 so that the dialysate fluid flows from the source to the first conduit;

12 fluidly connecting the second conduit to the extracorporeal circuit such that  
13 the substitution fluid is delivered and introduced into the extracorporeal circuit;

14 providing a control unit;

15 detecting a first characteristic of the dialysate fluid flowing within one of  
16 the first conduit and second conduit and detecting a second characteristic of the blood  
17 flowing within the extracorporeal circuit; and

18 inputting the detected first and second characteristics to the control unit,  
19 wherein the control unit is configured to prevent the flow and introduction of the  
20 substitution fluid into the extracorporeal circuit when at least one of the first and second  
21 characteristics meets a prescribed criteria.

1 38. The method of claim 37, wherein the first characteristic comprises a  
2 flow rate of the dialysate fluid and the second characteristic comprises a flow rate of the  
3 blood and the prescribed criteria comprises a situation where one of the dialysate flow rate

4 and the blood flow rate falls below a predetermined flow rate.

1 39. The method of claim 37, further including the step of:  
2 disposing a substitution fluid pump within the second conduit for diverting  
3 the amount of the dialysate fluid from the first conduit to the second conduit, wherein the  
4 control unit prevents the substitution fluid from being introduced into the extracorporeal  
5 circuit by controlling operation of the substitution fluid pump.

1 40. The method of claim 39, wherein detecting the first characteristic  
2 comprises the steps of:

3 disposing a pressure transducer within the second conduit for detecting a  
4 pressure of the dialysate fluid within the second conduit; and

5 transmitting a control signal from the control unit to the substitution fluid  
6 pump to turn to an OFF position when the pressure transducer detects a pressure below a  
7 threshold pressure value.

1 41. The method of claim 39, wherein detecting the first characteristic  
2 comprises the steps of:

3 disposing a pressure transducer within the second conduit for detecting a  
4 pressure of the dialysate fluid within the second conduit;

5 disposing a pinch valve within the second conduit for controlling the flow  
6 of the substitution fluid within the second conduit; and

7 transmitting a control signal from the control unit to the pinch valve to

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8 position the pinch valve in response to the control unit receiving input from the  
9 substitution fluid pump and the pressure transducer.

1 42. The method of claim 41, further including the step of:  
2 disposing an optical sensor disposed within the second conduit for detecting  
3 transmittance of fluid contained in the second conduit; and  
4 positioning the pinch valve by transmitting a control signal to the pinch  
5 valve from the control unit in response to input received by the control unit from the  
6 optical sensor.

1 43. The method of claim 42, further including the step of:  
2 closing the pinch valve when the optical sensor detects blood in the second  
3 conduit.

1 44. The method of claim 39, further including the steps of:  
2 disposing a flow switch within the first conduit for detecting a flow rate  
3 within the first conduit; and  
4 controlling the operation of the substitution fluid pump based on a position  
5 of the flow switch.

1 45. The method of claim 37, wherein detecting the first and second  
2 characteristics comprise the steps of:  
3 performing a first temperature decay measurement of the dialysate fluid in

the first conduit, the first temperature decay measurement being representative of a flow rate of the dialysate fluid;

performing a second temperature decay measurement of the blood in the extracorporeal circuit, the second temperature decay measurement being representative of a flow rate of the blood; and

wherein the control unit is configured to detect a decrease in the flow rate of the dialysate fluid by monitoring the first temperature decay measurement and a decrease in the flow rate of the blood by monitoring the second temperature decay measurement.

46. The method of claim 37, wherein the first detected characteristic comprises a flow rate detected by inductively monitoring a current applied to an inlet valve of the dialysis machine that is disposed within a conduit that carries the dialysate fluid to the first conduit and wherein the second detected characteristic comprises a flow rate detected by inductively monitoring a current applied to a motor that drives a blood pump disposed within the extracorporeal circuit.